

a pharmaceutically acceptable carrier.

22. The formulation of claim 21 wherein the microparticles are sized such that at least 50% of the microparticles are less than 3 μm .

23. The formulation of claim 21 wherein the biocompatible, biodegradable polymer comprises a copolymer of lactic acid or an enantiomer of lactic acid with glycolic acid or an enantiomer of glycolic acid.

24. The formulation of claim 21 wherein the at least one antigen comprises a *B. pertussis* antigen.

25. The formulation of claim 24 wherein the *B. pertussis* antigen is selected from the group consisting of inactivated pertussis toxin (PTd), filamentous hemagglutinin (FHA) and pertactin.

26. The formulation of claim 21 wherein the microparticles comprise at least two subpopulations of microparticles, each subpopulation comprising a different antigen entrapped or encapsulated by the biocompatible, biodegradable polymer.

27. The formulation of claim 26 wherein each of the antigens is selected from the group consisting of inactivated pertussis toxin (PTd), filamentous hemagglutinin (FHA) and pertactin.

28. A vaccine formulation for oral administration comprising:

a therapeutically effective amount of a coacervate, the coacervate comprising nanoparticles of at least one antigen and a biocompatible, biodegradable polymer, wherein the at least one antigen is entrapped or encapsulated by the biocompatible, biodegradable polymer and at least 50% of the nanoparticles are less than 600 nm; and

a pharmaceutically acceptable carrier.

29. The formulation of claim 28 wherein the biocompatible, biodegradable polymer comprises a copolymer of lactic acid or an enantiomer of lactic acid with glycolic acid or an enantiomer of glycolic acid.

30. The formulation of claim 28 wherein the at least one antigen comprises a *B. pertussis* antigen.

31. The formulation of claim 30 wherein the *B. pertussis* antigen is selected from the group consisting of inactivated pertussis toxin (PTd), filamentous hemagglutinin (FHA) and pertactin.

32. The formulation of claim 28 wherein the nanoparticles comprise at least two subpopulations of nanoparticles, each subpopulation comprising a different antigen entrapped or encapsulated by the biocompatible, biodegradable polymer.

33. The formulation of claim 28 wherein each of the antigens is selected from the group consisting of inactivated pertussis toxin (PTd), filamentous hemagglutinin (FHA) and pertactin.

34. A method of inducing a protective immune response against *B. pertussis*, comprising orally administering to a subject a therapeutically effective amount of a coacervate, the coacervate comprising microparticles of at least one *B. pertussis* antigen selected from the group consisting of inactivated pertussis toxin (PTd), filamentous hemagglutinin (FHA), and pertactin, and a biocompatible, biodegradable polymer, wherein the at least one antigen is entrapped or encapsulated by the biodegradable polymer and at least 50% of the microparticles are less than 5 μ m; and

~~a pharmaceutically acceptable carrier.~~

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35. The formulation of claim 34 wherein the biocompatible, biodegradable polymer comprises a copolymer of lactic acid or an enantiomer of lactic acid with glycolic acid or an enantiomer of glycolic acid.

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36. A method of inducing a protective immune response against *B. pertussis*, comprising orally administering to a subject a pharmaceutically effective amount of a coacervate, the coacervate comprising nanoparticles sized such that at least 50% of the nanoparticles are less than 600nm, the nanoparticles comprising at least one *B. pertussis* antigen selected from the group consisting of inactivated pertussis toxin (PTd), filamentous hemagglutinin (FHA) and pertactin, entrapped or encapsulated by a biocompatible, biodegradable polymer.

37. The formulation of claim 36 wherein the biocompatible, biodegradable polymer comprises a copolymer of lactic acid or an enantiomer of lactic acid with glycolic acid or an enantiomer of glycolic acid.

REMARKS

By this Amendment, claims 13-20 directed to methods of making vaccines are canceled without prejudice, and claims 21-37 directed to vaccine compositions themselves are presented.

Favorable reconsideration is respectfully requested in view of the foregoing amendments and the following remarks.

For example, newly presented claim 21 recites a vaccine formulation having a therapeutically effective amount of a coacervate. The coacervate comprises microparticles